PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

May 13, 2004

Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

04 MAY 14 PM 12:42
RECEIVED
OPPT CBIC

Subject: Comments on the HPV test plan for 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine

Dear Administrator Leavitt:

The following comments on the Ciba Specialty Chemicals Corporation (Ciba) test plan for 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Ciba submitted its test plan on December 15, 2003, for the chemical 1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine) (Irganox MD 1024, CAS RN 32687-78-8). The major uses and hazards for this chemical are well characterized in the test plan, and a concise and complete description is given for the required endpoints. The OECD SIDS data endpoints required by the program are fulfilled using existing data, and no new testing is proposed. Acute, repeat-dose, ecotoxicity, developmental toxicity, and genetic toxicity endpoints are satisfied through existing data from studies conducted according to OECD guidelines. Although the reproductive toxicity endpoint is not satisfied in a traditional manner, Ciba has proposed using data from repeat-dose studies where reproductive organs were examined histologically, plus the valid developmental toxicity study, to fulfill this endpoint. Ciba is conforming to both OECD and EPA guidance, and following the lead of several other sponsors, by using this strategy.

The EPA has clearly stated that an "evaluation of reproduction organs from . . . repeated-dose toxicity studies adequately address this [reproductive] endpoint." The OECD states in its Manual for Investigation of HPV Chemicals that when repeated dose studies that include the effects of reproductive organs and a developmental study are available, "the requirements for the reproduction toxicity endpoint would be satisfied" (Chapter 4).

Ciba has conducted a thoughtful analysis of the data and summarized this analysis in a clear and concise manner. We applaud Ciba's efforts at ensuring all available information is provided for this chemical and concur that no additional animal testing is necessary under the HPV Challenge Program. This approach is consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to toxicology.

Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research